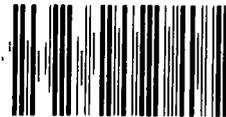


Briefing Report to the Chairman,
Subcommittee on HUD-Independent
Agencies, Committee on Appropriations
United States Senate

AIR QUALITY STANDARDS

The Role of the Health Effects Institute in Conducting Research



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UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

June 16, 1986

RES. COMMUNITY,
MIC DEVELOPMENT
DIVISION

3-223275

The Honorable Edward P. Boland
Chairman, Subcommittee on HUD-
Independent Agencies
Committee on Appropriations
House of Representatives

Dear Mr. Chairman:

As requested in your March 4, 1986, letter and in subsequent discussions with your office, we are furnishing you with information on the Health Effects Institute's (HEI's) efforts to provide the scientific research needed to better understand how motor vehicle emissions affect human health. Specifically, to assist you in funding decisions, you asked us to provide information on (1) the adequacy of HEI's organizational structure and internal controls, (2) the quality, credibility, and relevance of its research, (3) HEI's success in reducing adversarial disputes over technical issues and scientific data and (4) the cost-effectiveness of its research activities. On May 30, 1986, we briefed your office on the results of our work and, as requested, have prepared this briefing report summarizing the information discussed.

During the late 1970's a national debate took place about air quality standards. The need for objective, credible scientific studies to help guide the Environmental Protection Agency (EPA) in setting standards for motor vehicle emissions led to the establishment of HEI in 1980. It is a nonprofit corporation, cofunded by EPA and 24 automobile and engine manufacturers, organized to provide unbiased, independent research on the effects of motor vehicle emissions on human health. As of May 15, 1986, HEI had started 49 research projects, estimated to cost \$15 million. Through April 1986 four of the projects have been completed and HEI estimates that an additional 28 reports will either have been published or be in draft by late 1986.

The majority of our work was conducted at HEI's office in Cambridge, Massachusetts, and EPA headquarters in Washington, D.C. Most of the information we obtained is based on 61 interviews, the majority with a structured interview form. We were able to do only limited independent verification of the views these individuals shared with us.

On the basis of these interviews, the general consensus of EPA and industry officials is that HEI's products are credible and of high quality and that HEI has an independent organizational structure that ensures objectivity. Because of the difficulty in assessing the value of research, we were not able to determine whether HEI's research is cost-effective. However, on the basis of EPA's and the automotive industry's cofunding, EPA obtains \$2 of research activity for each federal dollar provided.

EPA and HEI differ on the relevancy of HEI's 49 research projects to current and emerging regulatory and public policy issues. HEI recognized early that, in exercising its independent scientific judgment, it would sponsor some research to answer scientific uncertainties related to health effects of motor vehicle emissions that regulators would not view as relevant research. Coincidental with our review, EPA began the first detailed assessment of the relevance of HEI's research to its regulatory needs. While in draft form and subject to change, the EPA assessment considers at least 44 percent of HEI's research budget to be highly relevant and at least an additional 25 percent to have low relevance. Although a disagreement about research relevancy exists, HEI and EPA officials have agreed that they can improve the dialogue about the definition of relevancy and the research projects to be performed.

It is too early to tell conclusively how beneficial HEI's products will be. However, the information we obtained suggests that HEI is performing credible and high quality research. Based on our work, we saw nothing which would indicate that funding should not be continued. If funding is continued, more open dialogue between EPA and HEI could help ensure that an increasing number of mutually agreed upon, relevant research projects are conducted.

As agreed with your office, we did not obtain agency comments, but we did discuss the results of our review with EPA and HEI officials and incorporated their comments where appropriate. We are sending copies of this briefing report to the Administrator, Environmental Protection Agency; Director, Office of Management and Budget; Chairman of the Board of Directors, Health Effects Institute; and other interested parties. If we can be of further assistance, please contact me or (202) 275-5489.

Sincerely yours,



Hugh J. Wessinger
Senior Associate Director

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ABBREVIATIONS

EPA	Environmental Protection Agency
HEI	Health Effects Institute
RFA	request for applications

BACKGROUND

- HEI was founded in 1980, jointly funded by the public and private sectors to conduct scientific research for regulatory purposes concerning the health effects to humans of motor vehicle emissions.
- HEI's independent Board of Directors established the Health Research Committee, which identifies potential research projects on the basis of input from its cosponsors, public interest groups, the scientific community, and its own perception of critical scientific gaps.
- Separate from the Research Committee, HEI established a Health Review Committee, which reviews draft research project reports to ensure the quality of the research results.
- HEI's staff scientists assist the committees in preparing requests for research proposals, evaluating and selecting research proposals, monitoring research, and reviewing and critiquing draft research reports.
- As of May 1986, HEI had funded 49 projects from among 306 proposals and was in the process of funding 6 additional projects from among another 48 proposals.
- As of May 1986, HEI had published three research reports and one research evaluation report. Twenty-eight additional draft reports are expected by December 1986. One completed project will not have a published report and two projects have been terminated.

SECTION 1

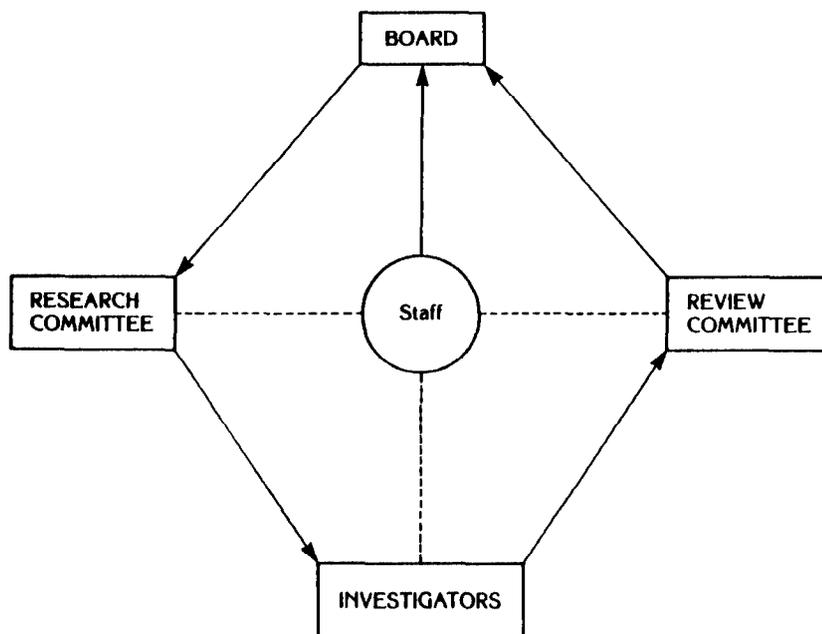
INTRODUCTION

BACKGROUND

The Clean Air Act authorized the Environmental Protection Agency (EPA) to set standards for motor vehicle emissions, including carbon monoxide and sulphur dioxide, to protect the public health and welfare. EPA attempts to base decisions on the permissible levels of such emissions on reliable, objective scientific information. During the late 1970's a national debate took place about EPA standards. Conflicting scientific information about the health effects of motor vehicle emissions led to different conclusions. EPA and automotive industry officials testified in congressional hearings in the late 1970's that regulatory research had focused exclusively on research necessary to determine specific standards rather than on an understanding of broader health effects issues. They agreed, in contrast, that existing basic research often ignored the important regulatory questions. As a result of this debate, the Health Effects Institute (HEI) was founded to provide independent research acceptable to EPA and the automotive industry.

Founded in 1980, HEI is an independently governed organization, jointly funded by the public and private sectors to conduct scientific research, for regulatory purposes, concerning the health effects on humans of motor vehicle emissions. HEI's activities are controlled by a Board of Directors, which has the authority to approve or disapprove the award of any contract. The Board relies on its Health Research and Review Committees to select the research projects and review the results of the research. These projects are also reviewed and critiqued by HEI staff scientists. Figure 1.1 illustrates the interrelationships of HEI's organizational components.

Figure 1.1: Organization of the Health Effects Institute



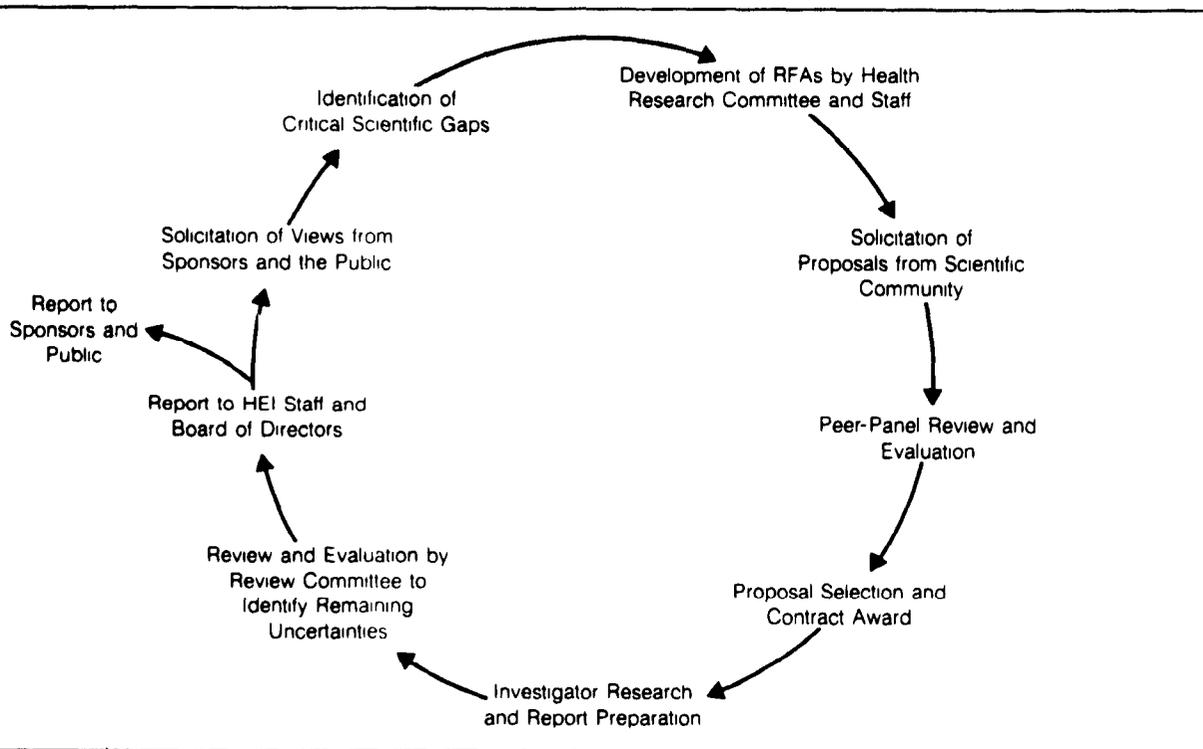
Source: HEI, Health Effects Institute: A New Approach to Regulatory Science, January 1985.

According to HEI officials, each HEI research project contains goals that range from providing information directly related to immediate regulatory decisions, such as identifying/quantifying the risks from specific pollutants, to developing information for future use, such as better methodologies for assessing the adverse effects on human health.

HEI established the process to independently identify and conduct high quality research

To achieve its stated purpose of providing the scientific research needed to gain a better understanding of how motor vehicle emissions affect human health, HEI awards contracts to qualified scientific researchers (principal investigators) for independent research. This research, which is estimated to cost between \$6 and \$7 million in both 1985 and 1986, is funded equally by EPA and the automotive industry. The industry sponsors include 24 manufacturers and distributors of cars, trucks, buses, and engines (motor vehicles) in the United States. (See app. II.) Although these sponsors identify research needs, they have agreed that HEI should act independently and as such they have no control over the selection, conduct, or conclusions of HEI's research projects. Figure 1.2 illustrates HEI's research and review process.

Figure 1.2: HEI Research and Report Cycle



Source: HEI, Health Effects Institute: A New Approach to Regulatory Science, January 1985.

Within the cycle of research, review, and reports, the Board of Directors has complete authority to determine what research projects are conducted and to ensure that those projects are conducted and reviewed by peers in a credible fashion. The Board has enlisted the aid of distinguished scientists to help plan its programs, select its individual studies, and evaluate the quality of the research. These scientists serve on either HEI's Health Research Committee or Health Review Committee. (See app. III.)

HEI's Health Research Committee identifies potential research projects, based on views and recommendations provided by EPA, the automotive industry, other government agencies, public interest groups, the scientific community, and its own perception of critical scientific gaps. The Research Committee's proposed research program is then presented to the Board of Directors for evaluation and approval.

The Research Committee then solicits proposals for actual research projects, based on its research program, through a request for application (RFA) process. It then examines the plans for the actual experiment (protocols) in each application for a credible, objective design. In this work administrative and research staff assist in preparing the research program, performing literature searches, drafting RFAs, and reviewing and rating applications.

Once the research projects are begun, HEI's staff scientists monitor them and coordinate with cosponsor scientists. These projects, according to HEI officials, generally continue for 3 years but may be extended or terminated early if HEI staff reviews show the quality of research warrants such a decision.

After a project is completed, the research results are evaluated by a different group of experts, the Health Review Committee, which has no role in designing the research project. Staff scientists also assist in reviewing and critiquing the draft research reports. The Review Committee makes a scientific determination about the quality of the research and evaluates the research's findings, in the context of existing knowledge, to

- identify remaining uncertainties,
- characterize the strength of the study,
- identify gaps in the research, and
- place this new information into the body of knowledge for industry and government's use in making decisions on human risk.

HEI includes these evaluations in the final report, which is transmitted to the sponsors and then made available to the general public. The Health Review Committee remains available to help interpret the study results. The committee makes no recommendations on how to apply the research to regulatory and social policy.

HEI's funded research
and its current status

Through May 1986 HEI has issued four requests for applications defining research necessary to fill certain research needs. HEI is currently conducting 49 research projects that include areas such as

- health effects of low levels of carbon monoxide;
- health effects of diesel vehicle emissions;
- effects of nitrogen oxides on lung development and lung susceptibility to infection;
- effects of nitrogen oxides, ozone, and diesel exhausts on susceptible populations; and
- identification of early indications of lung disease related to motor vehicle emissions.

Table 1.1 shows the number of responses from the scientific community and the number that HEI chose.

TABLE 1.1: HEI-Funded Research and Its Current Status

	<u>Date requests for application issued</u>			
	<u>July 19, 1982</u>	<u>June 30, 1983</u>	<u>July 9, 1984</u>	<u>July 24, 1985^a</u>
<u>Applications received</u>	153	84	69	48
<u>Projects approved</u>	25	15	9	6
<u>Report status</u>				
Completed and published	3	0	0	-
Completed but not to be published	1	0	0	-
Terminated	1	1	0	-
Draft under review	9	1	0	-
Draft expected by 12/86	10	7	1	-
Balance of ongoing projects	1	6	8	-

^aDraft contracts have been approved by HEI's Board of Directors but not made final.

OBJECTIVES, SCOPE, AND METHODOLOGY

- In a letter dated March 4, 1986, you asked us to examine the following issues:
 - the adequacy of HEI's organizational structure and internal controls to guarantee the independence and objectivity of research;
 - the quality of research funded by HEI and its credibility within government, industry, and academia;
 - the cost-effectiveness of HEI's research activities, including administrative support functions;
 - the success of HEI in reducing adversarial disputes over technical issues and scientific data; and
 - the relevance of the HEI research to current and emerging regulatory and public policy issues.
- Our work was performed between March and May 1986, primarily at EPA headquarters and HEI.
- Most of the information we obtained is based on 61 interviews, the majority with a structured form.
- Because of the limited time available for field work, we were able to perform only limited testing to verify what these individuals told us.
- We reviewed selected sponsor research-need requests, HEI requests for applications, actual applications received, minutes of HEI Board of Directors and Research and Review Committee meetings, files, and completed research reports. We also reviewed HEI's audited financial statements and the related management letters.

OBJECTIVES, SCOPE, AND METHODOLOGY

In a letter dated March 4, 1986, the Chairman, Subcommittee HUD-Independent Agencies, House Committee on Appropriations, asked us to examine the following issues:

- the adequacy of HEI's organizational structure and internal controls to guarantee the independence and objectivity of research;
- the quality of research funded by HEI and its credibility within government, industry, and academia;
- the cost-effectiveness of HEI's research activities, including administrative support functions;
- the success of HEI in reducing adversarial disputes over technical issues and scientific data; and
- the relevance of HEI research to current and emerging regulatory and public policy issues.

Our work was performed between March and May 1986, primarily EPA headquarters in Washington, D.C., and HEI's office in Cambridge, Massachusetts. Most of the information we obtained is based on 61 interviews, the majority with a structured form. We interviewed 22 EPA operational and research and development officials, 13 representatives of the motor vehicle industry, environmental and public interest group officials, 2 members of HEI's Board of Directors, 2 officers of HEI, 7 staff and staff scientists, 3 Research Committee members, 2 Review Committee members, and 5 principal investigators who had been funded by HEI. (See app. IV.) Because of the limited time available for field work, we were able to perform only limited testing to verify what these individuals told us. We did review selected sponsor search requests, HEI requests for applications, actual applications received, minutes of HEI Board of Directors and Research and Review Committee meetings, contract files, and completed research reports. We also reviewed HEI's financial statement audited by an independent certified public accounting firm and the management letters prepared by the firm. While we did review billings and payments of selected contracts and did limited testing of the financial records, the scope of our work did not include a full testing of HEI's system of financial internal controls.

HEI IS VIEWED AS HIGHLY
INDEPENDENT AND OBJECTIVE

- HEI is viewed by those we interviewed as highly independent and objective.
- No one perceived HEI as having any bias in its research or reporting.
- HEI organizational structure supports well its independence and objectivity.
- HEI has strengthened its procedures to further reduce the appearance of conflict of interest.

SECTION 2

HEI IS VIEWED AS A HIGHLY INDEPENDENT

AND OBJECTIVE ORGANIZATION

A major objective in forming HEI was to have an objective organization, independent of EPA and the motor vehicle industry, perform the scientific testing and research needed to determine the health effects of motor vehicle emissions. In this way, regulatory decisions could be made on the basis of independent scientific research results free of any taint of financial interest or preconceived policy judgment. Although very few research reports have been published, our review indicates that HEI's organizational structure and internal controls are adequate to ensure the independence and objectivity of the research conducted.

ORGANIZATIONAL STRUCTURE

HEI is a nonprofit corporation that has no shareholders or members. It is governed by a Board of Directors empowered to elect its own successors. The funding sponsors (government and industry) and other interested parties can make recommendations but have no power to elect or remove Directors. HEI's bylaws state that no person may serve on the Board of Directors who has financial ties to the motor vehicle industry or to any governmental agency responsible for the protection of the environment or the regulation of motor vehicles. The Board has final responsibility for all the activities of HEI, including the authority to approve or disapprove the award of any contract.

The establishment, management, and review of HEI's research program is the responsibility of two committees, independent of each other, operating under the supervision of the Board of Directors. The members of both committees are selected by the Board. The bylaws prohibit contracting for research with a member of either of the committees unless specifically approved by the Board of Directors. The Health Research Committee is responsible for establishing the priorities for HEI's research program, including the needs submitted periodically by cosponsors and recommending specific research projects in accordance with these priorities. The Research Committee accepts recommendations from the sponsors but is not required to include them in the research program.

The Health Review Committee is responsible for the quality of reports resulting from studies funded by HEI. The Review Committee subjects draft reports to a detailed, rigorous review process before publication with the intention of ensuring the highest possible scientific quality. The committee's comments are published with the final report, both to explain any limitations of the study and to place the results of the study in perspective they relate to the available body of scientific knowledge.

As with the Board of Directors, no individual who has a financial interest in the motor vehicle industry or any government agency involved in protecting the environment or regulating motor vehicles may serve on either committee. In addition, no committee member is allowed to serve on both committees.

The people we interviewed generally agreed that HEI has functioned independently in determining its research priorities and awarding research contracts. None of the interviewees questioned the objectivity of HEI's research program. However, a number of EPA officials indicated that, in their opinion, HEI may have been preoccupied with establishing independence from its sponsors. According to EPA officials, HEI thus funded a number of research projects that EPA considers of low relevance to its needs while simultaneously declining to fund some projects that EPA considered to be of higher priority.

INTERNAL CONTROLS

HEI has been audited annually since 1981 by a major independent public accounting firm. The resulting audit reports did not disclose any significant problems. We also reviewed the related management letters prepared by the accounting firm and determined through discussions with HEI officials, reviews of succeeding management letters, and limited testing of HEI's internal controls that the issues raised in the letters were satisfactorily resolved.

The most significant issue raised by the accountants regarding research objectivity was the need for HEI to adopt procedures and policies to avoid conflicts of interest; e.g., to deal with situations in which a member of the Research Committee might be affiliated with an organization being considered for a contract. We noted that one member of the Research Committee is the principal investigator on an HEI contract. However, his contract was approved before he was appointed to membership on the committee. We also noted that another member of the Research Committee is the president of a research institution having five research contracts with HEI. HEI has instituted a process requiring committee members to submit annual disclosure forms listing relevant affiliations and relationships. In addition, committee members are required to excuse themselves from any discussions or decisions about proposals from organizations with which they are associated and, in fact, we noted that this process is being used. In both of the above cases, the HEI Board of Directors reviewed the cases in detail and gave its approval.

HEI'S RESEARCH IS VIEWED AS
CREDIBLE AND OF HIGH QUALITY

- HEI's first four reports have been well received by all parties and are uniformly viewed as credible and of high quality.
- Among the reasons cited to support the views of credibility and high quality are
 - competition for contracts;
 - a mix of proved and innovative methodologies;
 - HEI's independence;
 - HEI's elaborate selection, monitoring, and review processes;
 - the funding and staffing stability; and
 - the prestigious and recognized authorities on HEI's boards and committees.

SECTION 3

HEI'S RESEARCH IS VIEWED AS

CREDIBLE AND OF HIGH QUALITY

HEI's purpose is to provide the scientific research needed to better understand how motor vehicle emissions affect human health; the results are to be used in establishing future regulations. In order for the results to be accepted as valid by all interested parties, HEI should be an objective, credible organization, funding high quality, unbiased research projects. This goal seems to have been achieved since the officials we interviewed generally considered the research and investigators to be credible and of high quality. Those interviewed gave a variety of reasons for their belief in the credibility and high quality, including the following:

- The degree of competition allows HEI to select from among a number of high quality proposals.
- HEI is attracting a mix of new researchers with proved methodologies and researchers with innovative methodologies.
- HEI's independence is attracting high quality researchers.
- HEI sets the right tone for the scientific community to attract high quality researchers.
- HEI's elaborate selection and monitoring processes demand high quality.
- HEI has done an excellent job of requesting proposals because of the high level of scientific expertise HEI has attracted to its committees.
- The intellectual depth of the organization is excellent.
- Stable funding and leadership exist in key scientific positions.
- HEI has attracted prestigious, recognized authorities who in turn attract quality researchers.
- HEI has attracted good scientists, but it is hard to use some of the research results for regulatory purposes.
- HEI is small enough to have quality interpersonal relations that are necessary to ensure a quality product.
- HEI has established a high quality peer review process that will ensure high quality products.

HEI'S COFUNDING IS ADVANTAGEOUS TO
THE GOVERNMENT, BUT WE COULD NOT
DETERMINE ITS COST-EFFECTIVENESS

- Because of the difficulty in assessing the value of HEI's research we could not determine its cost-effectiveness.
- However, the cofunding mechanism by EPA and the motor vehicle industry is financially advantageous to the government, assuming that the research HEI is funding would otherwise have to be funded totally by EPA.
- While our limited time for field work did not allow for a comparison of administrative support costs with similar organizations, we noted that HEI's capital investment has been minimal.

SECTION 4

HEI'S COFUNDING IS ADVANTAGEOUS TO THE GOVERNMENT, BUT WE COULD NOT DETERMINE

ITS COST-EFFECTIVENESS

It is very difficult to judge the cost-effectiveness of search activities since their worth may not be known for many years, if ever. In addition, research in support of regulatory needs, as funded by HEI, results in a body of knowledge to which it may be impossible to assign a value. In HEI's case this is compounded by the fact that the majority of research projects have not yet resulted in published reports. Because of the difficulty in assessing the value of research, we could not determine the cost-effectiveness of HEI's research activities. However, we noted that the dual-funding mechanism, under which HEI receives half of its funding from EPA and half from the motor vehicle industry, is financially advantageous to the government, assuming that the research funded by HEI would otherwise have to be funded totally by EPA.

HEI'S COST

We could not fully determine whether HEI's administrative support costs are reasonable because of time limitations in our view. To do so would have required work at similar organizations to develop a basis for comparison. However, we did obtain some cost information on HEI's operation and noted that HEI's capital investment is minimal. Investment in equipment and office furnishings amounts to approximately \$95,000, including approximately \$57,000 for computers and word processing equipment.

HEI's fiscal year is July 1 to June 30. Table 4.1 summarizes HEI's costs for fiscal year 1985, budget for fiscal year 1986, and costs incurred through March 31, 1986.

Table 4.1: Comparison of the Health Effects
 Institute's Actual Costs for FY 1985 and
 Budgeted Costs for FY 1986

	Fiscal year 1985		Fiscal year 1986				
	Actual costs		Total budget		Actual costs ^a		
	Amount	Percent	Amount	Percent	Amount	Percent of cost	Percent of budget
Research Projects	\$4,698,130	78.4	\$5,484,533	78.4	\$3,232,417	69.5	58.9
Scientific consulting:							
HEI committees	122,045		132,000		101,771		
Senior consultants	41,523		45,000		35,750		
General science consultants	67,318		65,000		62,828		
Conference, site visits, etc.	57,880		35,000		67,363		
Future strategy project	-0-		35,000		82,853		
Total consulting	\$ 288,766	4.8	\$ 312,000	4.5	\$ 350,565	7.5	112.4
Administrative expenses:							
Payroll - staff scientists	158,223		239,475		183,083		
- administration	114,908		168,276		125,210		
- secretarial	80,963		50,400		53,480		
Fringe benefits	53,835		81,192		64,849		
Payroll taxes	27,333		32,650		20,470		
Publications	13,726		104,000		128,584		
Travel	202,247		196,000		213,352		
Other	358,483		322,001		279,179		
Total administrative	\$1,009,718	16.8	\$1,193,994	17.1	\$1,068,207	23.0	89.5
Total	\$5,996,614	100.0	\$6,990,527	100.0	\$4,651,189	100.0	66.5
	*****	*****	*****	*****	*****	*****	*****

^aActual costs as of March 31, 1986.

Through 9 months of fiscal year 1986, expenditures on research projects amounted to 58.9 percent of the amount budgeted. HEI staff stated that expenditures for research projects will be close to the budgeted amount by the end of the fiscal year when all of the invoices are submitted by the universities and other institutions.

We noted that consulting costs have already exceeded the budget and that administrative costs are also higher than expected. The HEI Executive Director stated that a major reason for this is that the costs for one special project were higher than expected because of a decision to hold a conference in Dearborn, Michigan, for HEI's sponsors. He said this added approximately \$100,000 to various categories in the scientific consulting and travel areas. He said that printing and publication costs have also exceeded expectations and that HEI is taking steps to control printing costs before the reports currently under review are published.

ADVERSARIAL DISPUTES HAVE CHANGED

- EPA and the motor vehicle industry agree on the quality and credibility of HEI's four published reports.
- As increasing numbers of reports are published by the end of 1986, the willingness of cosponsors and others to accept the research results, and thereby reduce disputes, will become clearer.
- At the same time, a dispute exists between HEI and EPA over the relevancy of some of HEI's research.
- Some EPA officials characterize a number of HEI projects as not providing information that will be useful in establishing regulatory standards.

SECTION 5

ADVERSARIAL DISPUTES HAVE CHANGED

A major consideration in establishing HEI was the desire to reduce or eliminate disputes over the quality of the scientific research on which regulatory decisions would be based. As an independent, objective third party, HEI would fund research that would be free of any suspicion of financial interests or preconceived policy judgment. As a result, EPA, the motor vehicle industry, and other interested parties would be able to move on to discussions of what regulatory decisions should or should not be made on the basis of those results, rather than disputing the scientific research.

We believe it is still too early to tell whether HEI will be successful in removing the results of scientific research from the area of dispute. HEI has funded 49 research projects but to date has published only 3 research reports. In addition, HEI has also issued one report based on the research of other scientists. As of May 1, 1986, 10 draft reports were being reviewed by HEI, and an additional 18 draft reports are due to be submitted before the end of the calendar year. As increasing numbers of reports are published, the willingness of the sponsors and other interested parties to accept the research results and thereby reduce disputes over scientific research will become clearer.

We believe that the potential exists for HEI to succeed in reducing disputes over scientific research. As noted previously, we interviewed numerous EPA and motor vehicle industry officials, as well as officials from several environmental groups. These officials rated HEI as being an independent, objective organization engaged in high quality research. Given this assessment, it would seem reasonable to assume that the results of this research, in terms of scientific validity, will be acceptable to these organizations. We were told that the four reports published to date have been well received by the sponsors.

At the same time that HEI may be succeeding in reducing adversarial disputes between EPA and the motor vehicle industry over the quality of research results, a dispute exists between HEI and EPA over the issue of relevancy. While some EPA officials do not question the quality of the research being conducted, they characterize a number of projects as not providing information that will be useful to EPA in establishing regulatory standards. This issue is discussed in more detail in section 6.

THE RELEVANCE OF HEI RESEARCH IS
VIEWED DIFFERENTLY BY EPA AND HEI

- HEI recognized early that, as an independent scientific institution, it might not choose to fund a research program focused exclusively on questions EPA believed most relevant.
- HEI took steps to minimize this risk but may be giving relevance much more emphasis now than in its earliest years when establishing independence from its cosponsors may have had a higher priority.
- HEI and EPA have different definitions of what is relevant research.
- EPA has just begun its first broad-based assessment of the relevancy of HEI's research projects. The draft shows that EPA considers at least 44 percent of HEI's project funding to be spent on highly relevant research and at least 25 percent to be spent on projects of low relevance.
- Both HEI and EPA acknowledge that more needs to be done to resolve the relevancy issue.
- HEI and EPA have taken recent actions to improve the dialogue about relevancy.

SECTION 6

THE RELEVANCE OF HEI RESEARCH IS VIEWED DIFFERENTLY BY EPA AND HEI

HEI and EPA differ on the relevancy of HEI's 49 research projects to current and emerging regulatory and public policy issues. Many EPA officials believe a portion of HEI's research will not be usable to support regulatory decisions because of unrealistically high exposure levels. Other HEI projects are considered to be unnecessarily replicative of work by EPA or others. HEI's stated aim is to sponsor, review, and place into perspective the research projects needed to better inform regulatory decision makers concerning the standards needed for motor vehicle emissions. To meet this goal, HEI stated that it ought to attract the highest quality researchers from quality institutions who would use multidisciplinary approaches and to encourage a focus on methodological advances and innovation, not just research necessary for the next regulatory decision.

HEI RECOGNIZES THAT EPA MIGHT NOT REGARD ALL HEI RESEARCH AS RELEVANT

HEI recognized that, given an emphasis on innovation and basic research, the connection between some studies and the facts that motor vehicle emissions have on human health might not be clear to all observers. HEI also recognized that, as an independent scientific research institution, a possibility existed that the HEI Research Committee would initiate and direct a research program not focused exclusively on the regulatory questions for which EPA needed answers. HEI took a number of steps to minimize this risk. The Research Committee invited potential sponsors to meet and share what they considered to be the highest priority needs. This committee also solicited written statements of research priorities from its sponsors and other interested parties. In addition, HEI decided that it would, in some instances, request that researchers modify their proposals so that the proposed study might better address the relevant regulatory issues. Finally, HEI made abstracts of its contracts available to cosponsors for comment, although not until after the contracts had been awarded.

HEI RECOGNIZES THAT EPA MIGHT NOT CONSIDER SOME OF HEI'S RESEARCH RELEVANT TO ITS SHORT- TERM REGULATORY NEEDS

HEI issued its first requests for research applications on July 19, 1982. The majority of the resulting 25 contracts were signed in mid-1983. In early 1984 HEI distributed abstracts of the research projects to the sponsors and solicited their comments. In its reply EPA had two concerns, exposure levels and unnecessary replication. EPA noted that it was concerned that

some studies would be based on pollutant exposure levels exceeding the levels normally found in the atmosphere (ambient air). EPA believed that the use of such high levels would make the research results meaningless for regulatory purposes and limit EPA's ability to cite the results in criteria documents and staff studies supporting proposed regulatory decisions.

HEI's response was two-fold. First, it indicated to EPA that the Research Committee had suggested improvements that increased the relevance of the research but that limits exist in the extent to which a study to be performed in a given laboratory could be changed. Secondly, HEI stated that the objective of many HEI studies is to develop better methods for evaluating human health effects of pollutant exposure in ambient air. HEI believes that developing this methodology may require the use of high exposure levels in the initial stages of development to identify mechanisms, or causes, of injury at the molecular and cellular levels.

HEI acknowledged that studies at levels much higher than ambient air levels cannot be used directly in setting air quality standards. HEI stated, however, that such studies are important because they provide information on the actual mechanism of injury. This information will then enable researchers to design experiments to better understand the effects of exposure at ambient air levels.

INCREASED HEI EMPHASIS ON RELEVANCE TO COSPONSORS IN THEIR REQUESTS FOR PROPOSALS

In its third request for research proposals, dated July 9, 1984, HEI expanded and sharpened its guidance to potential applicants on the issue of exposure levels. HEI noted that while some studies might use exposures much higher than those experienced in ambient air, any study relevant to HEI's mission should provide information that is, finally, relevant to ambient exposures. They noted that when good research techniques required high exposures, it was an important aim of HEI that researchers explain the significance of these high exposures to ambient air quality.

A year later, in its request for proposals on the health effects of aldehydes, HEI specifically stated that it was interested in studies evaluating effects from exposure to low levels of aldehydes. HEI noted that exposures from motor vehicle emissions are less than those from cigarette smoke and residential and occupational exposures and that, if effects are found, the data should include exposure at concentrations of concern for motor vehicle emissions.

EPA CONSIDERS SOME HEI RESEARCH
PROJECTS TO BE OF LESS POTENTIAL
VALUE THAN DO OTHER INTERESTED PARTIES

In the course of our interviews, we found that automotive industry and public interest group officials generally considered HEI research to be relevant to regulatory needs. The HEI officials repeated the positions stated above, noting that the scientific judgments of HEI might not always coincide with EPA's immediate regulatory needs.

On the basis of our interviews of EPA officials, we found a wide range of opinions as to how relevant HEI's research is to regulatory needs. Many EPA program and research officials stated that some of HEI's research was highly relevant. Other research, ranging from 20 to 50 percent of the program, was considered to be of low relevance. Some EPA officials put most HEI research using higher than ambient air level of exposure or projected levels of auto emissions in this latter category. Some EPA officials also judge other research as being of little relevance because they have comparable results from their own or other research.

When asked why they believed HEI might not have negotiated exposure levels downward to more realistic levels, EPA officials speculated that it might have been due in part to

- HEI's early concern for establishing an independent research agenda and attracting the highest quality scientists to whom relevancy might not be as important as it is to EPA,
- EPA's not having fully communicated in its research priority needs those features it considered essential to make the research results more relevant,
- HEI and EPA officials differing in scientific judgment about the extent of remaining uncertainty about mechanisms of injury, or
- HEI's not knowing or appreciating that the Clean Air Scientific Advisory Committee of the EPA Science Advisory Board had directed EPA not to include any research results above the relevant exposure level in criteria documents to be used as support for standards.

ROAD-BASED EPA ASSESSMENT OF THE RELEVANCY
OF HEI'S RESEARCH IS JUST BEGINNING

In a 1980 press release on the establishment of HEI, the EPA Administrator stated

". . . EPA will be making recommendations on the Institute's research programs and protocols, and will be making at least an annual assessment of the Institute's activities. . . ."

The earliest assessment of the HEI program EPA made is one dated October 22, 1985. The assessment was prepared at EPA headquarters with opportunity for input or comment from field research scientists or program managers. The assessment, in summary format, portrays the HEI research as generally complementary to EPA's.

The most recent EPA assessment of HEI's program resulted from the attendance by seven EPA officials at the third annual HEI-sponsored conference for sponsors and principal investigators in Asilomar, California, February 16-19, 1986. EPA officials told us that they were provided more detailed research plans and data than they had seen in the past and that they were also provided an opportunity for unhurried informal interaction with HEI principal investigators. EPA officials told us that the detailed information obtained at the conference was the basis for EPA's project-by-project draft assessment of the relevancy of HEI's research.

EPA assessed 42 of HEI's research projects and rated them as being of low, medium, or high relevance. It did not assess seven projects because the report had been issued, the research had been terminated, or no abstract had been provided at Asilomar. Since the assessment is in draft form, these ratings are subject to change. Table 6.1 summarizes the assessment in terms of the number of projects and the dollar funding of projects begun through May 1986.

Table 6.1: EPA's Draft Assessment of Research Project Relevance

<u>Draft assessment of project relevance to EPA</u>	<u>Projects assessed by EPA</u>	
	<u>Number</u>	<u>Funding</u>
	(percent)	
Low	27	25
Low-Medium	17	12
Medium	17	17
Medium-High	5	2
High	<u>34</u>	<u>44</u>
	<u>100</u>	<u>100</u>

Although EPA's final criteria for determining relevancy are still uncertain, the use of exposure levels higher than ambient air levels and the duplication of research results already available seem to be important issues. Almost half of the projects rated by EPA as being of low or low-medium relevancy were characterized as using excessively high exposure levels or as unnecessarily replicating previous research.

EPA and HEI agree they define relevancy differently. EPA officials told us that they have provided HEI with more specific

ormation on EPA's research needs since its input into HEI's
st request for applications. EPA's draft definition of
evancy stresses that EPA should evaluate HEI's early projects
EPA's original request and not on research that became
ilable after a project began. HEI officials told us that HEI
EPA believe it is important to both HEI and the sponsors that
y reach a shared definition of relevance. The HEI officials
ted that EPA appears to be using a definition of relevance that
centrates on the research needed for the next regulatory
ion. HEI believes that its mission is not only to explore
r-term scientific issues but also to develop work enabling
entists to better extrapolate from animals to humans and to
velop the linkages among various kinds of research needed for
long term.

As a part of the continuing dialogue that both HEI and EPA
sidered vital to the relevancy issue, EPA gave the following
dance to HEI:

". . . We would like to emphasize one point dealing with
replication. EPA has learned that no matter how good one
considers an important study, the consequences of regulation
demand that corroborative data be obtained. If HEI concludes
that the key health issues have been captured in an
unreplicated study design already completed, then we urge HEI
to support that study's replication. . . ."

HEI officials do not believe that any of their research
jects are unnecessarily duplicative. In their opinion, when
e research results are considered in conjunction with the
ults of other studies, or when the longer-term objectives are
cluded, the projects are clearly relevant.

HEI officials agreed that the issues being raised in regard
relevance need to be resolved. In this regard, they said they
ld support any actions to improve communications between HEI
EPA.

EPA officials estimated the assessment might be completed in
ly summer 1986 and indicated the results would be communicated
HEI. EPA's assessment, including a clear statement by EPA of
e factors it used to determine relevance, should be useful in
osing the gap between EPA and HEI on the two definitions of
levant research. It would be helpful to HEI if EPA would
entify the exposure levels EPA considers relevant and the
pecific research studies that have already provided the results
at EPA feels HEI is unnecessarily duplicating.

JECT OF RELEVANCY
SUE ON HOW EPA VIEWS HEI'S
SPONSIVENESS AND PROPOSED BUDGET

As part of its budgetary process, EPA relies on five research
mittees to recommend annual research priorities and funding

levels to the EPA Assistant Administrator for Research and Development. One of the five, the Air Research Committee, is composed of senior research and development scientists and senior managers of air program offices. During the process of formulating the fiscal year 1987 research and development priorities, members of the committee recommended that the \$3 million proposed for HEI's fiscal year 1987 budget be split into two parts. One part, related to what some committee members view as the cost of projects not relevant to regulatory needs, was fixed at \$1.8 million and ranked 74th out of 76 projects.

EPA officials told us that, given the existing budgetary constraints under which EPA must operate, the research funded by HEI must be reviewed in terms of whether that research is providing the information needed by EPA in order to make regulatory decisions. They stated that if HEI is funding research that EPA cannot use in establishing regulatory standards and is simultaneously declining to fund research that EPA considered a high priority, then HEI should expect EPA to review carefully the appropriateness of HEI's future funding level.

On the other hand, HEI has stated that it would need a budget many times the current size in order to address adequately all of the priorities presented by EPA and the automotive industry. They noted that, in deciding which requests to include in their research agenda, HEI's Research Committee considers such factors as the state of the science in each area and the likelihood that a research program funded by HEI can make a difference in resolving regulatory problems, either now or at some point in the future.

HEI officials acknowledged that some research projects are not designed to find the answers to today's problems. Instead, they are expected to contribute to the available body of scientific knowledge and, consequently, could have an impact on future regulatory decisions. However, HEI, according to the officials, has made increasing efforts in the recent requests for applications to identify and fund research applications that contain the exposure levels desired by EPA.

HEI officials also stated that they have increasingly attempted to obtain detailed input from the sponsors on their specific needs. As an example, they stated that they asked EPA for comments on the proposed aldehyde research program before distributing the request for applications and have invited EPA representatives to attend the June 1986 Research Committee meeting.

RECENT HEI-EPA ACTIONS TO IMPROVE DIALOGUE ABOUT RELEVANCY

Just prior to or during our assessment, HEI and EPA had taken a number of actions that may help to increase the number of mutually agreed relevant HEI research projects. Specifically:

- HEI furnished abstracts of the highest quality and most relevant proposals received from its July 1985 RFA upon which EPA had been asked to comment.
- EPA furnished informal comments in time for Health Research Committee consideration and followed with written comments of a positive tone.
- HEI furnished more detailed project abstracts at the annual Asilomar Conference and the opportunity for wider interaction with principal investigators.
- EPA is in the process of conducting the first broad-based assessment of the relevancy of HEI's research to its regulatory needs. This may include an expanded definition of relevancy.
- HEI has suggested periodic review sessions between its Executive Director and members of its Research and Review Committees and senior EPA program and research managers. EPA has agreed to this.
- HEI invited senior EPA scientists to join the next Research Committee meeting to discuss relevancy and other issues. Three EPA scientists did participate.
- EPA has stressed to its managers that HEI will be for the foreseeable future an important source of health effects research and that communications with HEI are important.
- EPA has planned a review of HEI published reports for this fall to examine whether the research is making a difference in regulatory decisions.

OBSERVATIONS

- Although it is too early to reach definite conclusions on all the questions asked in the March 4, 1986, request, the consensus of individuals we interviewed is that:
 - HEI is an independent, credible, and objective sponsor of high quality research.
 - While HEI and EPA have not always had an effective dialogue to ensure that the research performed is considered mutually relevant, they have taken numerous recent actions to deal with this issue.
- The information we obtained suggests that the research HEI is funding is credible and of high quality. Based on our work, we saw nothing which would indicate that funding should not be continued.
- If federal funding is continued, more open dialogue between EPA and HEI could help ensure that relevant research projects are undertaken.

SECTION 7

OBSERVATIONS

Although it is too early to reach definite conclusions on the questions asked in the request of March 4, 1986, the consensus of the individuals we interviewed is that HEI has made progress in establishing itself as an independent, objective, and credible sponsor of high quality research. EPA and HEI have not yet had an effective dialogue to ensure that the research being performed, including specifics such as dosage levels, is relevant to motor vehicle emissions and the existing atmosphere. Both EPA and HEI have taken steps in recent months to deal with this issue. EPA's project-by-project evaluation of relevance should be useful. In addition, HEI's invitation to EPA officials to attend Research Committee meetings may improve communications.

It is too early to tell conclusively how beneficial HEI's products will be. However, the information we obtained, including interviews, research applications, contract files, minutes of meetings, and correspondence between EPA and HEI, suggests that the research HEI is performing is credible and of high quality. Based on our work, we saw nothing which would indicate that future funding should not be considered. If federal funding is continued, more open dialogue between EPA and HEI could help ensure that an increasing number of mutually agreed upon relevant research projects are undertaken.

REQUEST LETTER

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March 4, 1986

Honorable Charles A. Bowsher
 Comptroller General of the United States
 Washington, D.C. 20548

Dear Mr. Comptroller General:

The HUD-Independent Agencies Appropriations Subcommittee requests the General Accounting Office to conduct a program review and evaluation of the Health Effects Institute (HEI), located in Cambridge, Massachusetts. The HEI is cofunded by the Environmental Protection Agency and the automobile industry to coordinate research on the health effects of vehicle emissions. For the past several years the HEI has received about \$3,000,000 annually in Federal funds, although the President's budget makes no specific request for the HEI in 1987.

The Health Effects Institute was founded in 1980 in the hope that its joint funding and independently sponsored research could reduce disputes over scientific data and technical disagreements and permit debate to advance to the fundamental public policy issues. Since HEI's inception, no comprehensive evaluation has been conducted, and the need for such a review is made especially timely by the increasing pressures on EPA's research budget in 1987.

In assessing whether the HEI is fulfilling its promise and justifies continued Federal support, this study should examine the following issues:

- o The adequacy of the HEI's organizational structure and internal controls to guarantee the independence and objectivity of research;

Honorable Charles A. Bowsher

-2-

March 4, 1986

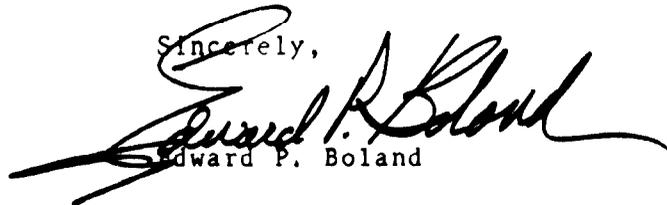
- o The quality of research funded by the HEI and its credibility within government, industry and academia;
- o The relevance of the HEI research to current and emerging regulatory and public policy issues;
- o The success of HEI in reducing adversarial disputes over technical issues and scientific data; and
- o The cost effectiveness of the HEI's research activities, including administrative support functions.

This evaluation, by its nature, must be largely subjective and qualitative rather than empirical. However, the Committee believes GAO is well equipped to undertake a comprehensive review in an objective manner. As a general approach, the Committee recommends that GAO identify and interview individuals in Federal agencies, the auto industry and academia who have been associated with, or have knowledge of the Health Effects Institute's work.

In order for the results of this evaluation to be available in time to assist the Committee's deliberations over 1987 funding decisions, a letter report is needed by May 30.

Thank you for your assistance.

Sincerely,



Edward P. Boland

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INSTITUTION OR OFFICE OF OFFICIALS INTERVIEWED

<u>ENVIRONMENTAL PROTECTION AGENCY</u>	<u>Number of individuals interviewed</u>
Assistant Administrator for Air and Radiation	1
Strategies and Air Standards Division	1
Office of Air Quality Planning and Standards	1
Office of Mobile Sources	1
Emission Control Technology Division	2
Science Advisory Board and Clean Air Scientific Advisory Committee	2
Acting Assistant Administrator for R&D	1
Office of Research Program Management	1
EPA Liaison to HEI	1
Office of Exploratory Research	3
Environmental Criteria and Assessment Office	1
Office of Health Research	2
Health Effects Research Laboratory	1
Cochairman or Members of the Air Research Committee or staff not otherwise noted	4
	<u>22</u>

Automotive Industry

General Motors Corporation	3
Ford Motor Company	3
Chrysler Corporation, Inc.	2
Volkswagon of America, Inc.	1
Engine Manufacturers Association	1
Motor Vehicle Manufacturers Association	1
American Motors Corporation, Inc.	1
Automobile Importers of America	1
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LTH Effects Institute

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Chairman and Members of Health Research Committee	3
Chairman and Member of Health Review Committee	2

APPENDIX IV

APPENDIX IV

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Principal investigators	<u>5</u>
	<u>21</u>

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Environmental Defense Fund	1
National Resources Defense Council	1
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